Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/14/2016 3:58:45 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: to avoid your team needing to comment on this again

Got it- passing along

On Apr 14, 2016, at 11:55 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Definition is now
Conditions of use
Potentially exposed or susceptible subpopulations

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/16/2016 9:32:14 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Nomenclature (4-16)

Michal,
Got it – checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Saturday, April 16, 2016 5:12 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Nomenclature

Try this version.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/18/2016 6:15:10 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA request - ITC

Michal, This TA responds to your request on the ITC. Please let me know if any questions. Thanks,
Sven

Have they recommended chemicals for testing that EPA didn't decide to test?

Yes. Over the years of TSCA implementation a number of chemicals were removed from the Priority Testing List (those recommended or designated by the ITC) by the ITC after further development of data and/or discussion by the ITC. In those cases, the rationale for removing them from the list is described in the relevant ITC report. Reasons have included the fact that testing or information which meets the need is already available or was otherwise being developed; investigation revealed that the chemical was no longer actively in commerce; or that the testing/data development recommended could be better provided by another federal entity. There are a number of recommended chemicals on the current list for which EPA has not yet required testing or proposed to the ITC for removal.

Does it function as intended?

The ITC has provided a forum for dialogue among federal agencies about testing and data needs related to chemicals. However, some of the procedures specified in TSCA have limited its usefulness. For instance, the statutory list of members does not include some key agencies (e.g., HHS/FDA and CPSC) and includes some who have been inactive. In addition, the ITC is not a FACA but a committee of federal employees representing their agencies (as opposed to their personal expertise). Nonetheless, TSCA imposes conflict of interest requirements on individual federal employees which has made it difficult to recruit members; in particular experienced senior staff from other agencies. The Senate bill and the House offer have provisions that appear to achieve the same outcome in terms of requiring EPA to consider the recommendations of other agencies, without the procedural difficulties and overhead required by current TSCA.

Is it an active body?

Yes, the Interagency Testing Committee (ITC) still exists and meets twice a year to review federal data needs for chemicals to add to the Priority Testing List (PTL). Although the ITC did meet on a semi-annual basis in 2014-15, it did not recommend any changes to the PTL. As a result, no report was published.

On Mar 16, 2016, at 2:50 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Can you get us some history of the ITC's work? Have they recommended chemicals for testing that EPA didn't decide to test? When/what? Does it function as intended? Is it an active body?

Thx

M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/6/2016 6:48:43 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request - replacement parts

Michal – got it – checking. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 06, 2016 2:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - replacement parts

Sven

A proposal is being floated as a potential solution to the replacement parts/designed by provision that would limit the provision's application to parts that are components of "durable goods" which is
"Durable goods," is a widely used term - adapted from 16 C.F.R. 802.1(d)* A good is "durable" if it is designed to be used repeatedly and has a useful life greater than one year.

I don't think this works as is – it may address a sub-set of the kid/infant products I've expressed concerns about, but doesn't address the couch seat cushion covers for obvious reasons.

But I am wondering whether there exists anything in regulation or SNUR/article precedent that your team can think up? we did work through some language months ago that related to the difficulty of re-designing articles of which the parts were a component, but that language was not accepted. I may tinker with it more as well, but in the meantime, can your team think of anything they've done before, even if not in the TSCA context, that would define a universe of articles/parts it applied to in a manner that limits/excludes some and keeps others?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
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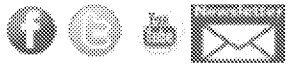

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/3/2016 4:31:14 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA request - section 26 and section 5 on fees

Michal –
TA responding to the request on section 26 and section 5 on fees. Please let me know if any questions.
Thanks,
Sven

Could you guys please look at section 26 just received from the House and describe workability or any other concerns?
Specific request on House fee language in addition to general questions on the section: Can fees be used to review PMNs or just "data" under section 5?

Response:
Page 1 lines 6-13: In response to your question about whether the collection of "data" under section 5 is a sufficiently broad provision to allow EPA to charge fees to the submitters of PMNs and use those fees to defray the cost of the collection and review of the PMN notice: EPA would take the position that it is, on the grounds that a PMN is itself "data" submitted under section 5. Section 5 is itself the provision that pertains to the review of PMNs. Analogous authority under current TSCA is the basis to assess current PMN fees. That said, current section 5 of TSCA arguably distinguishes between the PMN itself and data submitted with a PMN; to our knowledge, the argument has never been raised that section 26(b) does not authorize collection of fees for review of the PMN itself, but that point could be clarified.

Page 1, lines 12-13: This limitation on the use of fees is problematic from an implementation perspective, and apparently inconsistent with page 3 lines 5-8 and page 5 lines 16-17. The first of those references indicates that EPA can use fees to defray the cost of all activities associated with the chemical for which the fee is collected, and the latter reference supposes that EPA can charge fees to defray 25% of the cost of carrying out the whole new chemicals program, risk evaluation and risk management of existing chemicals (except for industry-sponsored chemicals which are supported at higher levels), the cost of implementing section 8

reporting requirements (including the new Inventory Reset), and the cost of protecting CBI and reviewing CBI claims. But the language on page 1, lines 12-13 apparently limits EPA to using fees solely to defray the cost of PMN collection and review, the cost of collecting test data on existing chemicals, and the cost of conducting risk evaluations. The other activities (including risk management rules that EPA could be legally obligated to undertake as a result of the risk evaluations) occur under provisions of TSCA other than sections 4, 5, and 6(b), and so there is significant doubt about EPA's authority to defray the costs of those activities.

Page 6 lines 9 and 19: Similar confusion could result from the specification that EPA set "the fee", in the case of industry-requested evaluations, at a level tied to the cost of the evaluation itself. This indicates that EPA cannot collect fees sufficient to cover the cost of any necessary associated rulemaking. EPA might be able to argue that it can do that under the general fee collection authority in (b)(1), but the reference to "the fee" could suggest that EPA has no authority to collect fees in this context other than for the evaluation.

Page 6 lines 12-13 and 22-24: The specification that fees for industry-requested risk evaluations cover EPA contractor costs, without a comparable specification for other fees, could imply that EPA cannot collect fees to cover contractor costs in any context of then industry-initiated evaluations.

Page 15 line 20 and Page 16 line 11: The point of this paragraph in the passed Senate bill was to ensure that the development of the key policy and procedure rules (especially the prioritization methodology rule and the risk evaluation methodology rule) does not become a litigation chokepoint for the implementation of the entire bill. Specifically, if this paragraph does not work properly, then EPA may face arguments in court that the particular implementation of TSCA reform should be stayed pending the resolution of litigation over general procedural rules, or that completed TSCA actions need to be vacated because they are inconsistent with policy and procedure documents that were not yet in effect at the time that the action was completed. There are three key issues here:

- First, Paragraphs A and B should have the same scope, as in the passed Senate bill (one now refers to "this subsection" and the other now refers to "this section").
- Second, the scope needs to be broad enough to clearly encompass the prioritization and risk evaluation policies. Since there could be ambiguity about whether they arise in Section 26, section 6, or both, the clearest drafting would be to have this provision refer to policies and procedures under "this Act."
- Third, the following language has been dropped from the Senate bill: "the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure." The policies and procedures in question are those completed after the substantive action was completed. The point of this provision was to prevent policy documents finalized *after* the finalization of a substantive action from being used to collaterally attack prior actions. The retained sentence establishes a separate point: the mere fact that an action is finalized prior to finalization of the policy document wouldn't mean that EPA has a duty to re-visit the action. The deleted language was seen as an important safe-guard, and a basis for regulatory predictability, in the case that it is many years before the policies and procedure documents are effective (e.g., due to litigation-driven delays). This language could be revised if its intent was not sufficiently clear, but simply deleting it will establish a clear implication that if EPA forges ahead with substantive implementation of TSCA reform while the P&P documents are being litigated, it does so at the peril of all its interim substantive actions being overturned, depending on the outcome of the P&P litigation.

Page 22 lines 3-9: The commenters are confusing two issues: Whether the enactment of the bill itself eliminates, modifies, or withdraws existing TSCA regulations, or whether EPA will need to eliminate, modify, or withdraw existing TSCA regulations in order to discharge its duties under the bill. This passage is only talking about the former issue. The commenters are talking about the latter issue. The point of this passage is that

conforming changes to EPA rules should occur by rulemaking--they don't occur automatically because TSCA changes.

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 01, 2016 8:06 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: TA request - section 26

Specific request on House fee language in addition to general questions on the section: Can fees be used to review PMNs or just "data" under section 5?

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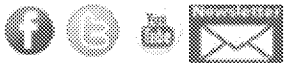
Connect with Senator Markey



On Apr 1, 2016, at 6:29 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven –

Could you guys please look at section 26 just received from the House and describe workability or any other concerns? After you finish section 5.

Thanks
Michal
<sec26_01_xml.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/9/2016 4:34:16 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TS request on PBTs

Michal - got it and will put in the queue a little later to allow folks to work on 6 and 14. Thanks,
Sven

On Apr 9, 2016, at 12:31 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Could you please review paragraphs 1-3 of this document to make sure it does what it is intended to do? I tried to be specific based on your TA about the 3 PBTs but may not have used the right terminology. Anytime today if possible, but if I am overloading you, mid-AM tomorrow should also be ok.

Thanks
michal
<04-09-16PBT (Conf Proposal).docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2016 4:03:13 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA Request on Other Federal Laws

Jonathan – got it – checking. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 25, 2016 11:59 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Suggested TSCA Language

Hi Sven, do you think anyone on your team is able to understand what these folks are proposing?

They have been pinging folks again.

From: James Williams [mailto:jwilliams@etc.org]
Sent: Wednesday, January 20, 2016 6:05 PM
To: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Suggested TSCA Language

Dear Dimitri and Jonathan as promised I am attaching our suggested TSCA legislative language to be included in the final TSCA bill. Please note that there are two attachments. One with suggested Senate legislative language and one with suggested House legislative language. As there is currently no clear answer as to which Chamber's bill will prevail I wanted to provide language for both bill for you to consider. The language in both attachments is very straight forward and self-explanatory. However, if you have any questions, please feel free to contact me by e-mail or at 202-731-1815 and I will be happy to address any questions you may have. Again, thanks for your time and consideration on this issue.

For the moment please keep this information close to the vest. As I am sure you can understand we are only sharing this with a few select staffers. I hope to follow up with House staff soon to get their imput.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/14/2016 6:34:37 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
Subject: URGENT - SEPW TSCA TA on chem id v. molecular structure

Dimitri – TA on chem id. Please see responses except #4. We're working on #4 and will get you what numbers we have as soon as possible. Note that the responses to #1 and #6 may have changed slightly from what I sent earlier. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
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1. Is it EPA's view that molecular structure is a component or element of chemical identity that may, but does not necessarily, unambiguously describe a chemical substance? In other words, does chemical identity include chemical molecular structure?

40 CFR 720.45 states that a specification of the chemical identity "includes" specifying: "For a Class 1 substance, a complete, correct chemical structure diagram; for a Class 2 substance or polymer, a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained."

2. Can a structurally descriptive generic name for a chemical substance unambiguously describe the chemical?

Not always. For examples, chemical substances of unknown or variable composition or biological material (UVCBs) are not described structurally.

3. Does EPA provide guidance on structurally descriptive generic names that enables an unambiguous description of a chemical substance? Is the Agency currently updating that guidance, or does it have plans to revise it?

EPA has guidance for generic names. However, a generic name, by definition, is designed to have broader applicability, as opposed to a chemical ID that identifies a specific chemical substance. There are no current plans to update this guidance.

Here is the link to the guidance:
https://www.epa.gov/sites/production/files/2015-08/documents/genericnames.pdf

4. How many health and safety studies published in 2015 contained confidential chemical identity information? How many of those confidential chemical identity claims did the Agency propose for disclosure? Please describe the overall trend in the number of health and safety studies with confidential chemical identity claims over the last years, and the trend in EPA efforts to disclose that information.

Working on the response

5. Existing Section 14(b) excludes process and mixture information from disclosure in a health and safety study. Other confidential information in a health and study, such as company identity or chemical identity, are not explicitly excluded

from disclosure, but are also not explicitly targeted for disclosure (particularly since section 14 directs EPA to only disclose the non-confidential portion of information that contains a mix of confidential and non-confidential information). Do either the House or Senate provisions amending section 14 change this interpretation in any way?

Current section 14 only governs what may not be disclosed. Inherent in that is that when CBI and non-CBI are mixed we may disclose only what is not CBI. And in some of our regulations we require that CBI be explicitly identified.

The House bill language on chemical identity in health and safety studies would be a departure from current 14(b), which at the very least allows chem ID to be disclosed as part of a health and safety study when its disclosure would not in turn disclose portions of a mixture or process information (and the Agency goes further, arguing in some cases that chem ID is always part of a health and safety study).

6. Does EPA read "molecular formula" being different than "molecular structure?"

Yes. Compare 40 CFR 720.45(a)(1)(iii) (requirement to include "molecular formula" in a PMN) and 40 CFR 720.45(a)(1)(iv) (requirement to include the "chemical structure diagram"). Two different chemical substances may have the same molecular formula, and yet have different molecular structures.

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, March 14, 2016 12:23 PM
To: Schmit, Ryan <schmit.ryan@epa.gov>
Subject: RE: EPA TA on chem id v. molecular structure

Also Ryan – maybe a quick question that could be helpful if getting through some of the other ones isn't as fast. In the Senate bill, (b)(8) of Section 14 goes to the protection of chemical identity and includes language saying "including the chemical name, molecular formula, CAS number…" Does EPA read "molecular formula" being different than "molecular structure?"

From: Karakitsos, Dimitri (EPW)
Sent: Monday, March 14, 2016 12:08 PM
To: 'Schmit, Ryan'
Subject: RE: EPA TA on chem id v. molecular structure

Thanks Ryan, this is very helpful but I have a few follow up questions. We are meeting with the House to discuss at 2pm so any quick feedback would be incredibly helpful but getting some answers anytime would be good to inform the discussion going forward. Much appreciate the help.

1. Is it EPA's view that molecular structure is a component or element of chemical identity that may, but does not necessarily, unambiguously describe a chemical substance? In other words, does chemical identity include chemical molecular structure?
2. Can a structurally descriptive generic name for a chemical substance unambiguously describe the chemical?
3. Does EPA provide guidance on structurally descriptive generic names that enables an unambiguous description of a chemical substance? Is the Agency currently updating that guidance, or does it have plans to revise it?
4. How many health and safety studies published in 2015 contained confidential chemical identity information? How many of those confidential chemical identity claims did the Agency propose for disclosure? Please describe the overall trend in the number of health and safety studies with confidential chemical identity claims over the last years, and the trend in EPA efforts to disclose that information.

5. Existing Section 14(b) excludes process and mixture information from disclosure in a health and safety study. Other confidential information in a health and study, such as company identity or chemical identity, are not explicitly excluded from disclosure, but are also not explicitly targeted for disclosure (particularly since section 14 directs EPA to only disclose the non-confidential portion of information that contains a mix of confidential and non-confidential information). Do either the House or Senate provisions amending section 14 change this interpretation in any way?

From: Schmit, Ryan [mailto:schmit.ryan@epa.gov]
Sent: Friday, March 11, 2016 1:57 PM
To: Karakitsos, Dimitri (EPW)
Subject: EPA TA on chem id v. molecular structure

Dimitri, per your request for TA on this issue:

In general terms, we believe "chemical identity" is best understood as a reference to information that would allow a person to unambiguously specify which substance entry on the TSCA Inventory they are referring to, whereas "molecular structure" is a reference to chemically descriptive information about the molecule itself (e.g., the atoms present in a molecule, their connections to each other, and their spatial arrangement). All chemical substances on the TSCA Inventory have a chemical identity. Some UVCB chemical substances on the TSCA Inventory may lack a known molecular structure.

"Molecular identity" appears only in the definition of what a particular chemical substance is. It is not itself defined. As EPA has used the term, it relates to the demarcation of one chemical substance from another. See: http://www.epa.gov/sites/production/files/2015-10/documents/nmsp-inventorypaper2008.pdf.

"Chemical identity" and "molecular structure" are listed as separate items in the list of types of information that EPA may require reporting on under Section 8(a)(2). Similarity of "molecular structure" is also one of the grounds to categorize chemical substances under section 26. The terms are not defined in the statute.

Thanks,
Ryan

Ryan N. Schmit
Special Assistant to Jim Jones, Assistant Administrator
Office of Chemical Safety and Pollution Prevention (OCSPP)
Telephone: 202-564-0610
Email: schmit.ryan@epa.gov

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/9/2016 4:19:13 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA Request on Chem ID

Michal,
This TA responds to the request on chem ID.

Your two emails seem to be asking questions in different directions: the first seems to be asking whether another basis could be added for allowing the withholding of chem id *in health and safety studies* (presumably something industry would want), and the second seems to be asking the very different question of whether there should be more stringent expiration or voiding conditions for chem id *outside the context of health and safety studies* than for other CBI (presumably something the NGOs would want).

Re your first question: although the statute allows for withholding of chem ID (or other info) in health and safety studies only on two bases (reveals process information of proportions of a mixture), EPA regulations allow withholding of specific chem ID on a third basis: where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study. That kind of provision could be codified in the bill.

Re your second question: The idea sounds like a beefing up of sec 14(c)(3) of the Senate offer, which presumptively voids CBI claims for chem ID and other information elements following a ban of a chemical. The triggering event for that provision could be moved up to the finding of unreasonable risk.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 11:20:40 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on ChemID

As part of your thought process here, and perhaps as an alternative option, let's think about a way where if chemID is kept CBI it goes public if a) epa makes a section 6 or 7 unreasonable risk finding about it and b) it has to be re-substantiated every 5/10 years with reasonable potential of an unreasonable risk being one of the things EPA has to consider.

Michal Ilana Freedhoff, Ph.D.

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202-224-2742

On Apr 9, 2016, at 5:40 AM, Freedhoff, Michal (Markey)
<Michal_Freedhoff@markey.senate.gov> wrote:
Good morning

We increasingly hear that "molecular structure" is a huge threshold issue for the House. It is for us too. I'm trying to learn more about the history here and also see if there exists middle ground - something akin to a 3rd condition for when chemID is withheld, like "keep molecular structures secret if X or Y, or unless X or Y". I'm not sure if a space like this exists for either side, but thought perhaps looking towards the recent decisions by EPA on why it did or did not release molecular structure could be useful.

Can you put together background materials or suggestions if you have any? Doesn't have to be before 1, but would be helpful if it was before 5 or 6 pm so I can review tonight as part of some of the other prep work I'm planning.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/12/2016 4:59:35 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Massachusetts Inquiry on TSCA Preemption re: h 253 - children's jewelry

Michal – you may be interested to know that we received a preemption question from the state of Massachusetts on a pending piece of state legislation – there's a link to the bill in the incoming below. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Moreschi, John (SEN) [mailto:John.Moreschi@masenate.gov]
Sent: Thursday, December 08, 2016 9:38 AM
To: O'Neil, Kelsey <Oneil.Kelsey@epa.gov>
Subject: RE: h 253 - children's jewelry

The bill is attached. It has passed the House and is being reviewed in the Senate by my office.

Thanks for your help. Without knowing where cadmium is in the EPA process I can't really determine what I can do in terms of preemption.

John

From: Moreschi, John (SEN)
Sent: Wednesday, December 07, 2016 4:02 PM
To: 'oneil.kelsey@epa.gov'
Subject: h 253 - children's jewelry

Hi Kelsey,

nice to speak to you again and thank you for your help. At this link is the bill at issue. https://malegislature.gov/Bills/189/H253 Looking forward to connecting.

john

John A. Moreschi
Assistant Counsel
Office of Senate Counsel
State House, Room 200
Boston, MA 02133
617-722-1470

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/22/2016 1:27:23 AM
To: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]; jonathan_black@tomudall.senate.gov
Subject: Sen. Booker TSCA TA request on Voluntary non-animal testing- followup

Adam,
This TA responds to the followup question on animal testing language and the proposed additional language.

The additional language does not eliminate the concern (although, looking at the language we sent, our TA was a little inexact). Our concern does not have to do with data already developed (which your language does take care of), but with the development of new data. The provision states that anyone developing information voluntarily "shall first attempt to develop the information by means of an alternative test method or strategy identified by the Administrator pursuant to paragraph (2)(C) before conducting new vertebrate animal testing." If EPA has not identified a relevant alternative method, that language could be read to bar anyone from conducting new vertebrate testing, because it is impossible to satisfy the condition precedent.

The issue could be addressed by re-wording the first sentence of (4)(A) as follows: "Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative test method or strategy identified by the Administrator pursuant to paragraph (2)(C), if the Administrator has identified such a test method or strategy for the development of such information, before conducting new vertebrate animal testing."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

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On Apr 21, 2016, at 7:59 PM, Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov> wrote:

Sven thank you for this.

If the proposed language that I indicated below was in fact added in -- on page 6 at the end of line 23 "Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator." after "vertebrate animal testing." -- would this language eliminate the concern stated in bullet # 2 below that "Read literally, the provision might completely bar anyone from submitted data voluntarily if EPA has not identified an alternative method. We understand the intent to be that the provision applies only to the extent that EPA has in fact identified alternative methods, but it is not actually (or at least clearly) so limited." ?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 21, 2016 7:44 PM
To: Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Sen. Booker TSCA TA request on Voluntary non-animal testing

Adam and Jonathan,
This TA responds to the request on voluntary non-animal testing.

Does EPA have a concern that voluntary tests look to non-animal testing first will lead to less information getting to EPA?

Response: EPA does have some concern that this provision could result in EPA's getting less information than it otherwise would, for two reasons:

- <!--[if !supportLists]--><!--[endif]-->Entities that might want to develop data but do not want to undertake whatever additional burdens might be associated with alternative methods identified by EPA might be discouraged from developing the data.
- <!--[if !supportLists]--><!--[endif]-->Read literally, the provision might completely bar anyone from submitted data voluntarily if EPA has not identified an alternative method. We understand the intent to be that the provision applies only to the extent that EPA has in fact identified alternative methods, but it is not actually (or at least clearly) so limited.

We also note that the provision could call into question EPA's authority to use information that is submitted without compliance with the provision. The Senate bill and offer provided that nothing in the provision required the Administrator to review the basis on which the submitter conducted the tests, but that text has been stricken.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

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202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Thursday, April 21, 2016 5:55 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Re: Sen. Booker TSCA TA request on Voluntary non-animal testing

And FYI this edit is now being proposed to the Voluntary Testing paragraph. The page/line track to the doc sent over last night:

4) Page 6, Line 23, please add the sentence "Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator." after "vertebrate animal testing.";

From: Kaiser, Sven-Erik
Sent: Thursday, April 21, 2016 5:50 PM
To: Black, Jonathan (Tom Udall)
Cc: Zipkin, Adam (Booker)
Subject: Re: Sen. Booker TSCA TA request on Voluntary non-animal testing

Ok

On Apr 21, 2016, at 5:47 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

I think still helpful.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Thursday, April 21, 2016 5:22 PM
To: Black, Jonathan (Tom Udall)
Cc: Zipkin, Adam (Booker)
Subject: Sen. Booker TSCA TA request on Voluntary non-animal testing

Adam and Jonathan,
Do you still need TA on this question? Thanks,
Sven

On Apr 20, 2016, at 6:06 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Sven, Adam with Sen Booker will elaborate, but there has been a concern raised about the Senate animal testing language that it will lead to EPA getting less information.

Does EPA have a concern that voluntary tests look to non-animal testing first will lead to less information getting to EPA?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/11/2016 10:16:45 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA Request on implementation dates followup

Michal,
This responds to the followup request on implementation dates language.

We think this does the trick, although would suggest one wording change for clarity. As drafted (per our TA), (B) has so many commas it's confusing and could be read such that "which shall be as soon as possible" modifies requirements for a ban or phaseout, instead non-ban/phaseout requirements as intended. To remedy this, we suggest the following wording fix:

(B) except as provided in subparagraph (C), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), ~~other than requirements for a ban or phase-out,~~ which shall be as soon as practicable,, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection(g);

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Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 11, 2016 4:46 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on implementation dates

Try this – by the time we are in a 6(a) rule how could reasonableness not be about costs when it comes to transition periods? I know re 6(g) but that's a fight I already had and I don't have time to have it again. ☺

(d) EFFECTIVE DATE.—(1) In any rule under subsection (a), the Administrator shall:
(A) specify the date on which it shall take effect, which date shall be as soon as feasible;
(B) specify mandatory compliance dates for all of the requirements under a rule under subsection (a), other than requirements for a ban or phase-out, which shall be as soon as practicable,, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection(g);
(C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);

(D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and
(E) provide for a reasonable transition period, subject to the compliance dates in subparagraphs (B), (C), and (D);
(2)) as determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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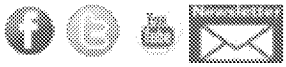
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 11, 2016 2:13 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on implementation dates

Michal,
This TA responds to the request on implementation dates.

Our only further TA is to double check that you understand that the "as soon as practicable," standard does not apply to the date by which the ban or phase-out must be fully in force (i.e., the end date for the phase-out). The only standard governing how long this end date can be pushed out is the direction under (d)(1)(D) to "provide for a reasonable transition period." Even though the decision that an eventual ban is necessary would be pursuant to risk-only analysis, the assessment of how quick of a phase-out is "reasonable" could still be cost-sensitive. This TA is also included in the attached document.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 11, 2016 11:19 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: implementation dates

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/20/2016 4:25:42 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on HLC section 26 (4-18) - followup
Attachments: SENATE_compared to_HOUSE Section 26 TA.docx

Michal – As we mentioned on the call and per our comment A2, we think the HLC language will significantly complicate EPA's budgeting process, but that it was something we could live with if necessary. However, we want to clarify that the characterization of the chemical-by-chemical approach for fees as merely a "hassle" was made assuming that our other comments on the crediting and availability of fees in subsection (b)(3) would be addressed – see comment A8. Without corrections here, the fee provisions would be problematic.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

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202-566-2753

From: Kaiser, Sven-Erik
Sent: Tuesday, April 19, 2016 7:27 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: TSCA TA on HLC section 26 (4-18)

Michal,
The TA below and attached responds to the request on HLC section 26 (4-18) including the question about partial risk evaluations.

We think that referencing the IQA in the manner suggested would make compliance with the IQA judicially reviewable in this context, setting a precedent in a statute with language allowing judicial review of IQA compliance. Up till now, IQA compliance has not been judicially reviewable.

Referencing the section 26 science provisions as you suggest would now subject those partial REs to standards that were not applicable at the time the risk assessments were completed. In essence, those requirements would become retroactively applicable to the completed risk assessments.

In that regard, we note that the new section 26 in the HLC version that we are still reviewing, as well as the last SLC version we have, still had the language at the end of the partial RE section (page 13, lines 18-19) that we had recommended striking in earlier TA. That language, "as in effect before such date of enactment", would

subject the rulemakings on these substances to the current section 6 requirements (e.g., least burdensome), which we did not think was the intent of this provision.

Additional Items of major policy note:

Page 1, line 17 - Retention of older language that might necessitate keeping separate accounts for what money can be spent on which chemicals … must be the same chemical for which fees collected.

Page 3, lines 2-6 - Retention of older "provisions" language that creates an argument we can't spend fees on risk management or CBI work

Page 18, line 7 - narrowed the scope of one of the provisions that is supposed to prevent litigation over policies and procedures from being used to undermine previously completed risk evaluations, etc.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 19, 2016 5:01 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: partial REs

For after you finish with 5, and only if it is not going to delay you sending 26 (it is a 26 issue).

I am wondering if this is why House keeps baking least burdensome back into the partial RE language in 26. I'm not at all interested in the suggested CSAC approach as it won't exist in the right timeframe. I'd be interested in your thoughts on the IQA idea, but am thinking it probably makes sense to cite to the science language in 26 in the partial RE section and be done. I'd be interested in your thoughts

michal

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

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Connect with Senator Markey

[DISCUSSION DRAFT]

SEC. ll. ADMINISTRATION OF THE ACT.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) in subsection (b)(1)—

(A) by striking "of a reasonable fee";

(B) by striking "section 4 or 5 to defray the cost of administering this Act" and inserting "section 4 or a notice or other ϕdata / *information? this needs to be decided, and if the change is being made throughout, there are other places in TSCA that may need amending*¿ to be reviewed by the Administrator under section 5, or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b), of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering sections 4, 5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, including

Commented [A1]: SLC version uses "information."

Since this is specifically a reference to information under section 4, this should be information to conform to the usage in section 4.

Commented [A2]: This phrase is not in SLC version.

Inclusion of this phrase will require EPA to maintain chemical-specific accounts to ensure that fees collected in relation to Chemical X are not spent on work in relation to Chemical Y, which will substantially complicate the budgeting process.

contractor costs incurred by the Administrator";

(C) by striking "Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100."; and

(D) by striking "submit the data and the cost to the Administrator of reviewing such data" and inserting "pay such fee and the cost to the Administrator of carrying out the activities described in this paragraph";

(2) by adding at the end of subsection (b) the following:

"(3) FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the 'Fund'), consisting of such amounts as are deposited in the Fund under this paragraph.

"(B) COLLECTION AND DEPOSIT OF FEES.—The Administrator shall collect the fees described in this subsection and deposit those fees in the Fund.

"(C) CREDITING AND AVAILABILITY OF FEES.—On request by the Administrator, the Sec-

Commented [A3]: "the" in SLC version

Commented [A4]: SLC says "subparagraph (A)" because they have imposed a new paragraph structure on this passage from current TSCA.

Commented [A5]: SLC amends paragraph (2) to refer to paragraph (4) rather than paragraph (1) respecting small businesses. HLC makes no change and retains current TSCA reference to (1). A change is necessary because reference to small business concerns in (1) has been deleted.

Commented [A6]: "referred to in this paragraph as the 'Fund' – SLC version

Commented [A7]: "the" - SLC

retary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated to pay or recover the costs incurred by the Environmental Protection Agency in carrying out the provisions of this title for which the fees are collected under paragraph (1).

"(D) USE OF FUNDS BY ADMINISTRATOR.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation for use in defraying the costs of the activities described in subsection (b)(1).

"(E) ACCOUNTING AND AUDITING.—

"(i) ACCOUNTING.—The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with

Commented [A8]: "for use in defraying the costs of the activities described in" – SLC

Retention of this House language may prevent EPA from spending fees on section 6 risk management work or on CBI work (since these activities are not provisions specifically associated with fees triggers)

Commented [A9]: "including contractor costs" – SLC

Commented [A10]: "paragraph (b)(1)" - SLC

sections 3515 and 3521 of title 31, United States Code.

"(ii) AUDITING.—

"(I) IN GENERAL.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

"(II) COMPONENTS OF AUDIT.—The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of—

"(aa) the fees collected and amounts disbursed under this subsection;

"(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of this title for which the fees may be used; and

"(cc) the number of requests for a risk evaluation made by manufacturers under ¢section 6(b)(4)(C)(ii)¿.

"(III) FEDERAL RESPONSIBILITY.—The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.

"(4) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(B) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray—

"(i) the lower of—

"(I) 25 percent of the costs to the Administrator of carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical

Commented [A11]: "of" – not in SLC version

substances under this title, other than the costs to conduct and complete risk evaluations under ø section 6(b)(3)(A)(ii) ¿; or

"(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and

"(ii) the full costs and the 50-percent portion of the costs of risk evaluations specified in subparagraph (D)(ii);

"(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(D) notwithstanding subparagraph (B)—

"(i) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to ø section 6(b)(3)(A)(ii) ¿, establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 6;

"(ii) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to ø section 6(b)(3)(A)(ii) ¿, and which are included in the 2014 update of the TSCA Work Plan for

Commented [A12]: "for chemical substances identified pursuant to [section 6(b)(4)(C)(ii)];" - SLC

Commented [A13]: SLC just says "(D)" This should reference "(D)", in line with SLC. (D)(ii) covers only the 50% share, whereas this provision refers to both full share and 50% share.

Commented [A14]: SLC version begins with "except as provided in clause (ii)..."

The SLC text is important because otherwise these paragraphs tell you to do inconsistent things with respect to a chemical that is on the Work Plan *and* the subject of a request.

Commented [A15]: Different section reference here.

Commented [A16]: "section 6(b)" - SLC

Commented [A17]: Different section reference here.

Chemical Assessments, establish the fee at a level sufficient to defray 50 percent of the annual costs to the Administrator of conducting the risk evaluation under section 6; and

"(iii) fees collected pursuant to clauses (i) and (ii) shall be applied by the Administrator only to defray the costs described in clauses (i) and (ii);

"(E) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) is applicable with respect to such meetings;

"(F) beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives pursuant to subparagraph (E), increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient to defray—

Commented [A18]: "Annual" is not in SLC version

Inconsistent use of annual cost vs. cost could create confusion --- e.g., "annual" not used in (i).

Commented [A19]: "6(b)" in SLC

Commented [A20]: "apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses." – SLC version

SLC version is the grammatically correct version. Passive voice construction of (iii) is not parallel with (i) and (ii).

Commented [A21]: "representatives of those parties" – SLC version

Commented [A22]: "or Subchapter II of Chapter 5 of title 5, United States code" – additional language in SLC version

SLC version would clarify that this rulemaking is not a negotiated rulemaking process.

Commented [A23]: "representatives of those parties" – SLC version

"(i) approximately but not more than 25 percent of the annual costs to the Administrator of carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, other than the costs to conduct and complete risk evaluations under section 6 for chemical substances under øsection 6(b)(3)(A)(ii)¿; and

"(ii) the full annual costs and the 50-percent portion of the annual costs of risk evaluations specified in subparagraph (D); and

"(G) if a notice submitted under section 5 is not reviewed or such a notice is withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(5) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for the Chemical Risk Review and Reduction program project of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for that program project for fiscal year 2014.

Commented [A24]: "of" not in SLC version

Commented [A25]: Different reference in SLC version.

"(6) TERMINATION.—The authority provided by this subsection shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress."; and

(3) by adding at the end the following:

"(h) *HOUSE OFFER*: SCIENTIFIC STANDARDS.—In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall consider, as applicable—

"(1) the extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for and consistent with the use of the information;

"(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

"(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

"(4) the extent to which the variability and uncertainty in the information, or in the procedures,

Commented [A26]: Language NOT in SLC version.

Commented [A27]: SLC version says "shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed in a manner consistent with the best available science, and consider…."

Commented [A28]: SLC version – "scientific information, technical procedures…"

Commented [A29]: "protocols, methodologies, or…"

Commented [A30]: "intended" – SLC version

measures, methods, or models, are evaluated and characterized; and

"(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, or models.

"(h) *ALTERNATE*: SCIENTIFIC STANDARDS.—In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

"(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

"(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

"(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

Commented [A31]: "protocols, methodologies, or...." – SLC version

Commented [A32]: "protocols, methodologies, or...." – SLC version

Commented [A33]: This appears to be the SLC subsection (h)

"(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

"(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

"(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.

"(j) AVAILABILITY OF INFORMATION.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this title;

"(2) any information required to be provided to the Administrator under section 4;

"(3) a nontechnical summary of each risk evaluation conducted under section 6; and

"(4) a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with and the results of those studies.

Commented [A34]: Not included in SLC version

"(k) REASONABLY AVAILABLE INFORMATION.—In carrying out sections 4, 5, and 6, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

"(l) POLICIES, PROCEDURES, AND GUIDANCE.—

"(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(2) REVIEW.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods

Commented [A35]: SLC version includes extra language here as follows: "including policies, procedures, and guidance related to the use of scientific information described in subsection (h), and for the purpose of making the basis of decisions under sections 4, 5, and 6 clear to the public."

and procedures for assessing and determining risk under this title; and

"(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

"(3) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6 as in effect before such date of enactment.

"(4) GUIDANCE.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Ad-

Commented [A36]: SLC version includes two additional paragraphs here: (3) Testing of Chemical Substances and Mixtures and (4) Integration of Prior Policies and Procedures

Commented [A37]: See paragraph (5) in SLC version

Commented [A38]: SLC version says "final"

House language has the advantage of not suggesting that a negative risk assessment is a final agency action prior to the finalization of the 6(a) rule.

Commented [A39]: Paragraph (7)(A) and (B) in SLC version, but identical.

ministrator. The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

"(m) REPORT TO CONGRESS.—

"(1) INITIAL REPORT.—Not later than 6 months after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of—

"(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under subparagraphs (A)(i) and (B) of section 6(b)(3), and the resources necessary to initiate the minimum number of risk evaluations required under øsection 6(b)(7)¿;

"(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under øsection 6(b)(3)(A)(ii)¿, the likely demand for such risk evaluations, and the

Commented [A40]: SLC version also includes a paragraph (6) on "Notice of Existing Information", which requires EPA to "take notice" of other information and Incorporate into risk evaluations.

Commented [A41]: Different cross references in SLC

Commented [A42]: Different cross reference in SLC

Commented [A43]: Different cross reference in SLC

Commented [A44]: "those" in SLC

anticipated schedule for accommodating that demand;

"(C) the capacity of the Environmental Protection Agency to promulgate rules under section 6(a) as required based on risk evaluations conducted and published under section 6(b); and

"(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 6(b).

"(2) SUBSEQUENT REPORTS.—The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.

"(n) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall publish an annual plan that—

"(1) identifies the chemical substances for which risk evaluations are expected to be completed that year and the resources necessary for their completion;

Commented [A45]: "the completion of the risk evaluations." - SLC

"(2) describes the status of each risk evaluation that has been initiated but not yet completed; and

"(3) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

"(o) CONSULTATION WITH SCIENCE ADVISORY COMMITTEE ON CHEMICALS.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish an advisory committee, to be known as the Science Advisory Committee on Chemicals (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise in the relationship of chemical exposures to women,

Commented [A46]: "on" in SLC version

Commented [A47]: "at a minimum" – SLC version